

## REMARKS/ARGUMENTS

Claims 1, 2, 4,5, 7-16 and 18-23 are currently pending. Claims 1, 2, 4, 5, 7-16 and 18-23 stand rejected. By this amendment, claims 1, 2, 4, 5, 13, 15, 16, 18, 22 and 23 are amended. Claims 24 to 28 are added.

### Applicant's invention

The instant invention provides an impact resistant substrate juxtaposed in close spatial relationship to the back of the wearer's neck. The substrate provides shock absorbing protection to the wearer's upper portions of the spine while the wearer is engaged in sports or other physical activities, said wearer who also may be wearing a helmet. The device protects the user's neck and other sensitive spinal areas not otherwise protected by a helmet or other prior art devices in the event he/she falls back against a curb, rail or other protrusion during cycling, roller blading, or the like. The art of record does not anticipate or suggest the instant invention.<sup>1</sup>

The applicant wishes to thank the examining attorney for withdrawing the §102 objection in regards to the Taylor prior art.

### § 103 Rejection combining Holmes and Spitler

Claims 1, 2, 4-5, 7-16, and 18-23 are rejected under 35 U.S.C. §103 as being unpatentable over the combination of U.S. Patent No. 3,657,739 (hereinafter "Holmes") and U.S. Patent No. 5,005,374 (hereinafter "Spitler"). The Examining attorney states that Holmes discloses:

A device to protect the neck and the base of the skull while allowing unimpeded motion of the head from either side to side or front to front including a first impact resistant pliable substrate(10) being rigid, col. 1, lines 71-75 than a second integral, molded and underlaying substrate (15) made of elastomeric material, col. 2, lines 21-26. Further, straps (13) extend from the substrate having closure/securing means as shown in figures 1 and 2. Also, the device extends to a region below the seventh vertebra as shown in figure 3.

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<sup>1</sup> See, for example, Specification, page 5, lines 18-23.

Applicant disagrees. Holmes does not protect the base of the skull. In fact, the concave indentation (element 26) in Holmes exposes the wearer's base of the skull to injury.

Holmes cannot be adapted to protect the wearer's neck inasmuch as attaching a neck protector in the concave indentation (element 26) would put pressure on the wearer's neck. This is because Holmes straps wrap around the wearer's torso and so pull the protection device over the wearer's shoulders putting pressure on the wearer's back. Adding a neck protection device to Holmes would result in the Holmes device pushing on the back of the wearer's neck with the full weight of the device. Such a protector would be unbearable for the wearer.

The instant device, as now claimed, extends up toward the wearer's skull without putting pressure on the back of the wearer's skull. Holmer's, on the other hand, extends only downwardly (see convex portion 27) from the wearer's skull.

The present invention, as claimed in the amended list of claims, is significantly distinct. As a primary matter, it is suggested that the Holmes invention and the present invention are designed to provide completely different types of protection. (See Affidavit). The present invention is worn *in a reversed position* to that of the Holmes invention. The Holmes invention is worn with the elongated part (see 25 in Holmes figure 1) facing *down*. In the present invention, the protective protrusion (see 21 in figure 1) is worn *upwards*. This is not a merely semantic difference. Instead, the upward configuration is the salient feature of the present invention. As is discussed below, the wearing configuration difference points to the distinct features of the two approaches to protecting the wearer's backside.

First, as the Examiner asserts, the Holmes invention does extend to a region below the seventh vertebra. In fact, the Holmes figure 3 that the Examining Attorney points to shows the invention reaching below the shoulders and consequently well into the thoracic vertebra such that Holmer reaches far down the wearer's back. Protection of the shoulder area and the back is not crucial to the safety aspects of the present invention. As amended, claims 1, as well as claims 4 and 5, limit the bounds of the present invention to an embodiment that is primarily concerned with protecting the cranial region and the uppermost vertebrae rather than the wearer's lower back.

It is clear from the Holmes disclosure and figures 1-3 cited by the Examiner that it is impossible for the Holmes invention to offer any protection for the upper regions of the neck. This protection is foreclosed in the Holmes invention. Figure 1 clearly shows that there is a concave indentation 26 in the Holmes invention where a neck protecting piece would otherwise have to be installed. Further, the neck protection cannot merely be added to the Holmes disclosure. If a neck protection piece is added in place of the rounded indentation 26 of Holmes figure 1, the neck protection would impact the wearer's neck and put pressure on the wearer's neck (see Affidavit) rather than protecting the wearer. Furthermore, the strap configuration on the Holmes invention causes the entire guard piece to rest against the wearer's back at the rounded indentation. This differs from the free-hanging features as now claimed (see below). Therefore, again, if a neck guard was added to the indentation, it would essentially put the entire weight of the Holmes invention on the wearer's neck.

Amendments to claim 1 along with claims 4 and 5 distinctly presently limit the present invention to one that is intended to protect the cervical vertebrae, which reside superior to the thoracic vertebrae. Further new claim 28 clarifies that the present invention includes protection for these upper parts of the neck with a free-hanging descending end. The introduced limit providing that the protection extends from thoracic vertebrae to base of cranium has support on Page 6, lines 10-19. Again, this could not be achieved with the Holmes invention, even if it was combined with a piece protecting the neck.

Further, unlike any device using the base elements of Holmes combined with a neck protector, the present invention, as claimed in claim 28, features a free-hanging downwardly extending end. The downward portion of the Holmes device is not free hanging but instead rests against the wearer's back. Combining Holmes with a neck protector does not affect whether the downward portion will hang freely. The fact that the downward portion is free hanging is an important element of the present invention as it causes the present invention to be comfortable to wear.

Also, as now claimed, the protection device is free hanging in that it does not rely on straps around the wearer's body. Instead, the neck protection device attaches to the neck of the wearer and as therefore free hanging allowing the wearer to move freely.

To modify Holmes to be free-hanging would obviate Holmes, inasmuch as the later requires straps to confer stability against the torso of the wearer (see lines 40-44, column 2 of Holmes). The Holmes invention does not hang freely, but instead is kept in place by the straps around the wearer's body. Support for the free hanging status of the invention is found on Page 6, lines 5 to 9.

Other problems are created by the Holmes invention, alone or combined with a neck protector. The larger size of the Holmes invention adds to the weight of the protective collar, and creates a number of problems not present in the present invention. First, because the protective collar reaches further down the back than the present invention, it is difficult to keep in a single location, and further it is difficult to position it in a stable manner. Consequently, as Figures 3 and 4 show, the straps holding the Holmes invention in place must wrap around the wearer's torso and so the Holmes invention cannot be worn during sports activities that require uninhibited motion. (See Affidavit.) Additionally, the straps of the Holmes invention are coupled together as a belt, again to create some semblance of stability.

The present invention achieves protection for the wearer's sensitive cranial areas without encumbering the wearer as the Holmes invention must. Further, unlike the Holmes invention, the straps of the present invention wrap around the wearer's neck and not the torso. Consequently, the present invention is far less cumbersome and can be worn and removed with ease:

The Examiner suggests that the Holmes invention can be combined with the disclosure of the Spitler patent so as to render the present invention obvious. The Spitler neck cooler does feature two substrates as was previously claimed. However, the Spitler reference neither discloses the present invention individually or in combination with Holmes.

First, as was explained above, no neck protector can be added to the Holmes invention. Creating such a combination would choke the wearer or put significant pressure on the back of the wearer's neck.

The suggested combination of the two inventions also defeats the purpose of the Spitler device. The embodiment disclosed in Spitler which includes a neck device is intended to function as a temperature control collar. Given that its sole purpose is

cooling, the neck device must have minimal weight so as not to burden the wearer. Combining the thermal wrap with any features not designed for cooling of the body would defeat the purpose and benefits of the Spitzer invention. Also, as Spitzer explains, the neck is the only place where contact should be made since significant amounts of heat are exchanged through the wearer's neck.

Spitzer also does not come close to disclosing the salient features of the present neck protector. As is claimed in new claims 25 and 27, the benefit of this protective device is that even when the user is wearing the present invention, there is access to the user's trachea. Such a tracheal shield cannot be accommodated in the Spitzer device. Further, providing for such access would defeat the sole purpose of the Spitzer neck wrap. The goal of the Spitzer device is to cool down the user by exchanging heat through the neck. The Spitzer device envisions maximum cooling per lateral length of the neck wrap. Putting a tracheal shield into it would decrease its cooling benefits. (See Affidavit.) Additionally, unlike the present invention, which is meant to be worn in conjunction with other elements, the Spitzer device can easily be removed in case emergency access to the trachea should prove necessary. In fact, the Spitzer device is meant to provide easy access so as to facilitate exchanges of temperature control packs. Support for the claimed tracheal shield is found in the specification on Page 8, lines 18-25 and it is shown of figure 3.

As such, the Spitzer invention does not disclose the salient features of the present invention. Further, any combination of Holmes and Spitzer would defeat the purpose of both of these inventions. Overall the present invention provides protection to upper neck that is not disclosed in the references either separately or when imprudently combined. As such, withdrawal of the Section 103 rejection based on the combination of Spitzer and Holmes is hereby solicited.

Claims newly added further demonstrate features of the present invention that are not disclosed in the cited prior art. New claim 26 covers the feature of the invention wherein the second, inner surface is found only along the edges of the invention. Neither Holmes nor Spitzer suggest this approach. Spitzer, whose purpose is cooling, will only operate desirably if the entire inner cooling surface makes contact with the wearer's skin. The present invention departs from these approaches and can feature

the inner substrate only along certain delimited areas. This allows the present invention to be worn more comfortably. Any protection device will only be worn if it is sufficiently light so as to not fatigue the wearer.

Further differences between the prior art are demonstrated by present amendments to claim 2, which now states that the inner substrate can be arranged so as to distribute force of impact to multiple locations, and prevent the brunt of the impact from being felt in any one location. Granted, Holmes does teach the benefits of offering additional protection to certain parts of the back. However, Holmes and other prior art do so through the addition of padding. For example, as disclosed in Figure 1 of Holmes (number 12), Holmes adds additional padding to cover particularly sensitive areas. This approach is markedly different than what the present invention teaches. Rather than adding additional padding on the outside of the protector, the present invention seeks to rearrange the pre-existing padding so as to achieve the impact distribution features. This approach is not disclosed by Holmes or other references that would rather add more weight to the device rather than taking a more sophisticated approach as disclosed by the present invention.

An additional improvement in the present invention over the prior art is found in new claim 24, which covers the fact that device can function as a removable shield used in combination with, and reversibly attached to a protective headwear to confer uninterrupted protection from top of a wearer's head to below the wearer's seventh vertebrae. The Holmes invention along with Spitler cannot be combined to create a protective device of such broad scope.

Consequently, as presently presented, claims 1,2, 4-5, 7-16, and 18-23 along with new claims 24-28 covering the invention demonstrate ways in which the present neck protector is significantly different from the inventions presented by Holmes in conjunction with a neck wrap as disclosed by Spitler and other prior art cited by the Examiner.

The federal circuit has repeatedly determined that if references cannot be combined to form the invention at issue, the invention at issue is not obvious in light of

the references.<sup>2</sup> Here, the proposed combination of Holmes with a neck protection device such as Spitler would result in an unbearable contraption that would defeat the very purpose of the present invention, that purpose being protecting the neck and upper areas of the spine. Also, it should be noted that in *KSR v. Teleflex*, the Supreme Court did not undermine these decisions. In fact, the Supreme Court would have considered whether the combination of the references was possible, but the parties failed to raise the issue during the earlier proceedings.<sup>3</sup>

In conclusion, inasmuch as any combination of Holmes and Spitler would result in a non-operable invention, such a combination cannot render the present invention obvious, as it is a *functioning* neck protector.

#### **§ 103 Rejection combining Holmes, Spitler and Hujar**

The examiner rejects claims 4 and 5 as unpatentable over Holmes and Spitler in view of US Patent 5,557,807, (hereinafter "Hujar").

The above discussion demonstrates ways in which the claims of the present invention differ from Holmes and Spitler. As such, the below discussion focuses on the disclosure of Hujar and its relationship to the present invention.

Hujar discusses in but one paragraph<sup>4</sup> that a sheet may be placed near the back of the wearer's head to help cool the wearer.

The present invention does far more than what Hujar discloses. The present invention is an integrated upper neck protection device which, pursuant to claims 4 and 5 can be coupled to a helmet or integrated with a helmet. Claims 4 and 5, pursuant to their present amendments, are limited to the neck protection device as described in

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<sup>2</sup> For example, the Federal Circuit has stated that "If when combined, the references would produce a seemingly inoperative device, then they teach away from their combination." *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999) citing *In re Gordon* 733 F. 2d 900 (Fed. Cir 1984). Also, very recently, the Federal Circuit held that where the offered combination of prior art would result in serious negative consequences, the combination could not be obvious. *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 2007 U.S. App. LEXIS 15349, at \*21 (June 28, 2007, Fed. Cir. 2007).

<sup>3</sup> See Section III A of the opinion. The Court stated: "Teleflex argues in passing that the Asano pedal cannot be combined with a sensor in the manner described by claim 4 because of the design of Asano's pivot mechanisms. ... In light of Teleflex's failure to raise the argument in a clear fashion, and the silence of the Court of Appeals on the issue, we take the District Court's conclusion on the point to be correct." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1744 (2007).

<sup>4</sup> Hujar Col. 8 Lines 19-26.

independent claim 1 whose purpose is to create an uninterrupted zone of neck and spine protection. Hujar does nothing to disclose such a zone of protection.

In effect, Hujar is nothing more than a cooling drape which provides no protection other than cooling or heating. In fact, Hujar is completely inappropriate to accomplish the goals of the present invention. Ice is to melt on the curtain and the dripping cold water is to ensure that the curtain is kept cold. The Hujar cooling neck curtain accomplishes the cooling through movement of air between the neck and the chilled curtain. Again, in order to accomplish the cooling, there must be a space between the wearer's neck and the cooling surface of Hujar so that air traveling therebetween is cooled.

The present invention is intended as a neck protection device, and as such, it must make contact with the wearer's neck. Contact with the wearer's neck would defeat the cooling feature of Hujar. Furthermore, the cooling device in Hujar is shown placed on the outside of the cap so as to avoid contact with the person's neck as contact with a wet neck protector would result in an unpleasant sensation to the wearer.

Claims 4 and 5 do not claim the process of attaching something (such as a cooling curtain) to a head-piece. Instead, these claims depend on the limitations of claim 1 which limits the scope of claims 4 and 5 to upper neck protectors. Consequently, the prior art would have to show a neck protection device capable of being attached to a head-piece. The invention disclosed by Hujar cannot be adapted to this purpose as it would prevent Hujar from fulfilling its purpose.

As such, suggesting that the present invention can be derived from Hujar is inappropriate since Hujar cannot be modified to perform the same tasks as those of the present invention. Attempting to do so would prevent Hujar from performing its cooling tasks.

Consequently, as Hujar in combination with Holmes and Spitler do not specifically disclose each and every element of claims 4 and 5, these claims are allowable.

#### Secondary Considerations

The applicant believes that the present invention solves a long-felt need in the field. Immobilization devices are known, but only treat the patient *after* an injury has

taken place such as the art of record. Nonetheless, according to the National Head Injury Foundation and the Center for Disease Control (CDC) approximately 50,000 people die each year in the United States from Traumatic Brain Injury (TBI). Over one million (1,000,000) people are seen in emergency departments with TBI. A TBI event occurs every 21 seconds in the United States. The largest segment of these patients are between ages of 15-19 years of age, and the number one cause is falls.

The present invention seeks to prevent injuries by protecting the upper neck regions. The prior art devices, while useful for preventing some injuries are clearly not sufficient as these injuries continue unabated. Unlike the prior art, the present device is designed to be light-weight and worn with minimal interference to activity. As such, the present device can be worn by young athletes and would prevent TBI events from falls. If the prior art devices were sufficient, the number of injuries would not be as high.

Pursuant to the above discussion, claims 24 to 28 have been added. Enclosed please find a fee payment check for \$455.00 meant to cover the \$395 small entity fee RCE fee and a one-month extension of time. The Office is authorized to charge any deficiency or credit any overpayment to the undersigned's Deposit Account No. 501709.

An earnest attempt has been made hereby to respond to the July 24, 2007 Advisory Action in the above identified matter. Applicant submits that the application is now in condition for allowance. If the Examiner feels that a telephonic interview will expedite allowance, she is respectfully urged to contact the undersigned. Claims 1,2, 4, 5, 7-16, and 18-28 are pending. Allowance is hereby solicited.

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Respectfully submitted,

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